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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,108	10/19/2000	Louise Elizabeth Donnelly	7500-0010	7685

23980 7590 03/18/2003

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/694,108	Applicant(s) DONNELLY ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-37* is/are rejected.

7)☒ Claim(s) *19 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1, 11, 12, 13, 14, 15, 18, 24, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by FISCHER et al., 6,329,422.

2. Claims 1-10, 16, 17, 21-23, 26-28, 29 and new claims 31-34, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over FISCHER et al., supra in view of GOLDBERG et al. (journal article), and PEZZUTO et al., and Goodman & Gilman's Ninth Edition and American Drug Index, Facts and Comparisons. New claims 31-34 and 37 fall under the rejection of claims 1-10, 16, 17, 21-23, 26-28, 29 under 35 U.S.C. 103(a). These claims will be specifically addressed below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Nov. 4, 2002.

No claims are cancelled. New claims 31-37 are added. Claims 1-37 are currently pending.

The previous objection to the oath/declaration set forth in paragraph 1 of the office action mailed July 31, 2002 **is withdrawn** in view of Applicant's amendment, the remarks contained therein and the application data sheet.

The previous claims objection set forth in paragraph 2 of the office action mailed July 31, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claims rejections under 35 USC 102(a) and (e) set forth in paragraphs 3-7 of the office action mailed July 31, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of claims 1, 11, 12, 13, 14, 15, 18, 24, 25 under 35 USC 102(e) set forth in paragraph 8 of the office action mailed July 31, 2002 have been considered but are not found to be persuasive. It is Applicant's position that Fischer et al. is directed to a method for enhancing chloride transport as a way of treating cystic fibrosis. Moreover, Fischer discusses asthma as a disorder associated with excessive mucous accumulation, although it is well known that asthma is an inflammatory disorder. Applicant contends that the treatment of excessive mucous would not have any bearing on the treatment of an inflammatory disorder as claimed.

Said arguments have been considered but are not found to be persuasive.

According to page 1, lines 10-17 of Applicant's specification it appears as if the limitation "inflammatory respiratory disorder" encompasses a number of conditions such as asthma, bronchitis, cystic fibrosis Therefore, the Examiner submits that although the prior art methods don't specifically disclose a method for treating "inflammatory respiratory disorders", the prior art does disclose treatment of the disorders (asthma, bronchitis, cystic fibrosis) encompassed by the limitation "inflammatory respiratory disorder" using resveratrol. Thus the prior art of record continues to anticipate Applicant's claimed method.

Applicant's arguments traversing the claims rejection under 35 USC 103(a) set forth in paragraphs 9-11 of the office action mailed July 31, 2002 have been considered but are not found to be persuasive. It is Applicant's position the combination of the prior art fails to disclose or fairly suggest the claimed method and compositions. Specifically, Fischer et al. is directed to a method for enhancing chloride transport and does not relate to inflammatory disorders. Concerning claim 29, this claim is directed to a pharmaceutical formulation for treatment of inflammatory respiratory disorders, not for the treatment of disorders associated with defective chloride transport. Additionally, Applicant argues that Fischer et al. cannot be effectively combined with Goldberg. Goldberg et al. relates to a method for quantitating trans-resveratrol in wines and merely mentions in the introduction that resveratrol is present in plants that have been used in Japan as a source of herbal medications for the treatment of inflammatory disorders. Such a brief mention of plants used in Japan is not suggestive of nor is it enabling for the use of resveratrol in the treatment of inflammatory disorders. At best, the Goldberg article makes the claimed method obvious to try.

With respect to the Pezzuto reference, Applicant contends that Pezzuto is directed to a method for preventing or treating skin conditions using topical administration of resveratrol and the combination of Pezzuto and Fischer do not render the claimed invention obvious. Finally, concerning claims 26-28 the combination of Goodman & Gilman's as well as the American Drug Index does not teach or suggest the limitations of the pending claims.

Said arguments have been considered but are not found to be persuasive.

According to page 1, lines 10-17 of Applicant's specification it appears as if the limitation "inflammatory respiratory disorder" encompasses a number of conditions such as asthma, bronchitis, cystic fibrosis Therefore, the Examiner submits that although the prior art methods don't specifically disclose a method for treating "inflammatory respiratory disorders", they do disclose treatment of the disorders (asthma, bronchitis, cystic fibrosis) encompassed by the limitation "inflammatory respiratory disorder" using resveratrol. Regarding the use of the Goldberg and Pezzuto references, although the Goldberg reference relates to a method of quantitating trans-resveratrol in wines and does not teach or suggest the use of resveratrol to treat inflammatory respiratory diseases and Pezzuto is drawn to treating or preventing skin conditions, the Examiner relies on these references for the teaching that resveratrol is known to have anti-inflammatory properties. Moreover, Pezzuto discloses pharmaceutical compositions containing resveratrol and anti-inflammatory agents or antibiotics which disclose and thus suggest the limitations in claims 26 and 29. Finally concerning 26-29 as well as new claim 31, the Examiner maintains that it would have been obvious to one of ordinary skill in the art to modify the methods and compositions of FISCHER et al. to additionally administer bronchodilators such as theophylline and salmetrol xinafoate, as taught by American Drug Index, or the use of antiasthmatics such as cromolyn sulfate, glucocorticosteroids and beta-adrenergic agonists, (as taught by Goodman & Gilman's, pages, 666, 667-668), because one of ordinary skill in the art would reasonably expect these bronchodilators and/or the antiasthmatics to be equally effective in treating the patients suffering from asthma. In other words, one of ordinary skill in the art

would reasonably expect that the combination of resveratrol and bronchodilators and/or antiasthmatics would successfully treating a subject suffering from asthma.

Concerning claim 32 and 33, Fischer et al. disclose compositions for endopulmonary and/or intranasal inhalation administration or the compositions may be administered orally (col. 12, lines 61-63).

In addressing claims 29, 34 and 37, these claims are drawn to the intended use of the claimed formulations; however, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the resveratrol containing compositions of Fischer et al. and Goodman & Gilman's and American Drug Index, which are structurally similar to the claimed formulations, are capable of treating inflammatory respiratory disorders.

New Ground(s) of Rejection

Applicant's amendment necessitated the following new ground of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Goodman, 6,022,901 (already of record) or Fischer et al., 6,329,422 (already of record) in view of Remington's Pharmaceutical Sciences, 15th Edition.

GOODMAN discloses pharmaceutical compositions containing resveratrol, cis-resveratrol, trans-resveratrol, a pharmaceutically acceptable salt, ester, amide, prodrug, or analog thereof. The compositions may be in a form suitable for nasal aerosol or inhalation. Please see the abstract; col. 7, line 66 to col. 8, line 7 and lines 25-27.

FISCHER et al. disclose pharmaceutical compositions for treating cystic fibrosis, chronic bronchitis or asthma, the compositions comprising active agents such as resveratrol and pharmaceutically acceptable aerosol propellants useful for endopulmonary and/or intranasal inhalation administration. Please see col. 6, lines 58-67; col. 11, lines 47-60; col. 13, lines 24-30; claim 28.

Goodman or Fischer do not disclose that the inhalation compositions are in the form of a dry powder; however the Examiner refers to Remington's Pharmaceutical Science which discloses that the use of powders as a pharmaceutical dosage form is known and used in aerosols and insufflations (please see page 1554, left hand column, first full paragraph). Additionally, Remington's teaches that insufflations are finely divided powders introduced into body cavities such as the nose and throat (please see page 1575, Insufflations). Finally, Remington's discloses that the particles size of the powders may vary (please see page 1554, left hand column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation compositions of Goodman or Fischer to be in a dry powder form because, in view of Remington's disclosure, one of ordinary skill in the art would reasonably

expect inhalation compositions in dry powder form to effectively deliver the active agent to a patient in need thereof. Furthermore, Remington's discloses that powders possess certain advantages such as stability and rapid therapeutic effect (please see page 1571, second column, Advantages).

In addressing claims 35 and 36, the use of a pharmaceutical sugar as a carrier is obvious and well within the capability of the skilled artisan. As far as claim 36 is concerned, since the efficacy of the formulation is dependent upon particle size of the dry powders, as suggested by Remington's, it would have been obvious to one of ordinary skill in the art to further modify the inhalation compositions such that the particle size of the powders is effective to optimize the compositions therapeutic effect.

Conclusion

Claims 1-18 and 21-37 are rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

March 17, 2003

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200